Attachment C

NOV 1 9 2010

510(k) Summary

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Contact Information: Constance Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace
Fridley, MN 55432

Submission Date: April 16, 2010, Revised November 12, 2010

Device Name and Classification: Sensometrics® Software, Intracranial Pressure Monitoring Device,
Class II, 21 CFR 882.1620
Product Code: GWM

Equivalent Device Identification: NeuroSystems 1™ Monitor, K050702, Integra MPM-1 Monitor, K962928, Phillips IntelliVue Mp40, K032858

Device Description: Sensometrics® Software is a secondary display system that collects together on a single large color display screen the measured pressure variables relevant to the multi-modality monitoring of the patient in a neurosurgical intensive care unit. It receives digital inputs from primary monitors used in the measurement of intracranial pressure, arterial blood pressure and cerebral temperature. The Sensometrics® Software displays the measured and derived variables in digital trace form and can store and display trends over periods of up to 240 hours.

Intended Use: Sensometrics® Software is intended for use by a qualified nurse or physician to display variables from existing legally marketed primary measuring devices used to monitor neurosurgical and neurological patients. The parameters displayed by the Sensometrics® Software include intracranial pressure, arterial blood pressure, oxygen, core/cerebral temperature, and these are continuously trended in charts. The presentation of both measured parameters and the relationships between them is intended as an adjunct to the information provided by existing primary monitors. The Sensometrics® Software should not be used alone as the sole basis for decisions as to diagnosis or therapy.

Summary of Substantial Equivalence: Sensometrics® Software is similar in design, intended use and performance to the NeuroSystems device. It has the same intended use in that it is an adjunct to primary measuring devices. There are no major differences between the two devices. Sensometrics Software is also substantially equivalent to the Phillips and Integra device. All three devices have the same outputs. No new issues of safety or effectiveness are introduced by using this device.

Comparison Table

Parameter	Proposed device	Predicate Device 1	Predicate Devices 2 & 3
Identification	Sensometrics Software	NeuroSystems 1 Monitor, K050702	Phillips IntelliVue Mp40, Integra MPM-1
510(k) No.	K101133	K050702	K032858, K962928
Technology	Intracranial pressure monitoring device	Same	Same
Intended Use	Sensometrics® Software is intended for use by a qualified nurse or physician to display variables from existing legally marketed primary measuring devices used to monitor neurosurgical and neurological patients. The parameters displayed by the Sensometrics® Software include intracranial pressure, arterial blood pressure, oxygen, core/cerebral temperature, and these are continuously trended in charts. The presentation of both measured parameters and the relationships between them is intended as an adjunct to the information provided by existing primary monitors. The Sensometrics® Software should not be used alone as the sole basis for decisions as to	Same	Same except these devices are the primary measuring devices

	diagnosis or therapy.		
Variables measured	The measured parameters are described above in detail. All parameters have their origin from the measured signal which is equivalent to the predicate device.	Same but might have different presentation policy with regard to pressure parameters presented.	Same
Design:	Software installed on a PC connected via a RJ45/RS232 cable to primary monitors	Monitor connected to primary monitors	Primary Monitor
Data Storage	Dynamic and limit depends on configuration	1, 2, 8 or 24 hrs.	Unknown
Trace Form	Digital	Analog or digital	Analog or digital

Summary of Testing:
Sensometrics® Software has undergone testing on several levels:

- Module/Unit testing
- Subsystem testing
- Integration test
- Verification and validation testing throughout the development life cycle
- Final acceptance testing of the final product

The device performed according to specifications.

The Software was also compared with the Phillips and Integra devices in a performance comparison test. The test objective was to compare Mean ICP, Mean ABP, systolic pressure output, diastolic pressure output and cerebral temperature output between the three devices. The test results show that the parameters computed by Sensometrics software are equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

dPCom AS
c/o Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
435 Rice Ccreek Terrace NE
Fridley, MN 55432

NOV 19 2010

Re: K101133
Trade/Device Name: Sensometrics® Software
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: August 25, 2010
Received: August 31, 2010

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101133

dPCom AS
Oslo, Norway

Indications for Use

510(k) Number (if known):

Device Name: Sensometrics® Software

Indications For Use:
Sensometrics® Software is intended for use by a qualified nurse or physician to display variables from existing legally marketed primary measuring devices used to monitor neurosurgical and neurological patients. The parameters displayed by the Sensometrics® Software include intracranial pressure, arterial blood pressure, oxygen, core/cerebral temperature, and these are continuously trended in charts. The presentation of both measured parameters and the relationships between them is intended as an adjunct to the information provided by existing primary monitors. The Sensometrics® Software should not be used alone as the sole basis for decisions as to diagnosis or therapy.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Hoffmann

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K101133